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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/920,272	08/22/1997	FREDA MILLER	CIBT-P01-120	8297

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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/04/2002

37

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/920,272

Applicant(s)

MILLER ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32,33,41-47,49-52 and 54-63 is/are pending in the application.
- 4a) Of the above claim(s) 61-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32,33,41-47,49-52 and 54-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Claims 38 and 53 were cancelled, and claims 32-33, 41-44, 46-47, 49-52, 54-60 were amended in Paper No. 35, 9/24/2002. Claims 32-33, 41-47, 49-52, 54-63 are pending. Claims 61-63 stand withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 32-33, 41-47, 49-52, 54-60 are under consideration.

Response to Arguments and amendment

Applicant's amendment and arguments filed 9/24/2002 have been fully considered but they are persuasive in part.

The rejection of claims 32-33, 41-47, 49 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter has been obviated by Applicant's amendment, and is thus withdrawn.

The rejection of claims 32-33, 41-42, 49-60 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, i.e. the specification as originally filed does not provide support for the invention as now claimed: a "cellular composition" of stem cells, has been obviated by Applicant's amendment, and is thus withdrawn.

The rejection of claims 32-33, 38, 41-47, 49-63 under 35 U.S.C 112, first paragraph, because the specification, while being enabling for neuronal progenitor/precursor cells, does not reasonably provide enablement for stem cells, has been obviated by Applicant's amendment, and is thus withdrawn.

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The rejection of claims 32-33, 38, 41-47, 49-60 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been obviated by Applicant's amendment, and is thus withdrawn.

The rejection of claims 49-60 under 35 U.S.C. 102(b) as being anticipated by Avoli et al. (1994), has been obviated by Applicant's amendment, and is thus withdrawn.

The rejection of claims 32, 43-47, 49, 54-57 and 59-60 under 35 U.S.C. 102(a) as being anticipated by Sosnowski et al. (1995), has been obviated by Applicant's amendment, and is thus withdrawn.

The rejection of claims 41 and 42 under 35 U.S.C. 103(a) as being unpatentable over Sosnowski et al (1995) in view of La Salle et al. (1993), has been obviated by Applicant's amendment, and is thus withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32-33, 41-47, 49-52, 54-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sosnowski et al (1995), in view of U.S. Patent No. 5,824,489 (Anderson et al.).

Sosnowski et al.(page 38, column 1, second paragraph to column 2, first paragraph) teaches a primary culture of olfactory epithelium isolated from adult mouse. Based upon immunoreactivity (page 45, column 1, fourth paragraph) to antibodies specific for intermediate filament proteins, the cells present in cultures were identified as neurons, glia or epithelial cells. Thus, Sosnowski teaches progenitor cells isolated from peripheral tissue, in this instance olfactory epithelium, of a postnatal mammal. The cells isolated by Sosnowski et al. have been shown to be multipotent, due to the presence in culture of several cell types. Sosnowski et al. teaches that the cultures established from regenerating olfactory tissue after chemical insult exhibited a range of neuronal yields (page 47, column 1, third paragraph). Cellular components of the cultures produced by Sosnowski et al. tested positive for keratin, as well as 200 kD and 160 kD neurofilament proteins, indicating the establishment of mixed olfactory epithelial cultures containing olfactory neurons (page 46, column 1, first paragraph). The cells comprising the composition of Sosnowski et al. were isolated from peripheral tissue, i.e. olfactory epithelium, in a fashion similar to the cells claimed in the instant application. The cells in the composition taught by Sosnowski et al. differentiate to produce neuronal cells, as do the cells of

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the instant application. The cells in the composition of Sosnowski et al. can be transplanted into the CNS of a mammal, as can the cells of the instant application.

The cells of Sosnowski et al. do not express nestin or are transfected with a heterologous gene. The '489 patent discloses multipotent neural stem cells can be derived from neural epithelial tissue from the brain and/or spinal cord of the adult central nervous system or neural epithelial tissue which may be present in tissues comprising the peripheral nervous system. In addition, the '489 patent discloses that such multipotent neural stem cells may be derived from other tissues such as lung, bone and the like (column 5, lines 40-47). The cells disclosed in the '489 patent express nestin (column 6, lines 1-5). The '489 patent discloses that the cells may be transfected with a vector (column 3, lines 59-63). Therefore it would have been obvious to one of skill in the art at the time the invention was made to make a population of neural stem cells from a mammal from peripheral tissue, wherein the neural stem cell expresses nestin. The motivation is provided in the '489 patent which discloses that the ability to isolate and grow mammalian neural crest stem cells in vitro allows for the possibility of using said stem cells to treat peripheral neurological disorders in mammals, particularly humans.

Conclusion

No claim is allowed.

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245.

The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.
Patent Examiner
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November 21, 2002